IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

PRESSURE PRODUCTS MEDICAL SUPPLIES, INC.,	§	
	§	Civil Action No. 9:06-CV-121
Plaintiff/Counter-Defendant,	§	
	§	JURY TRIAL
	§	
	§	Judge Ron Clark
v.	§	Magistrate Judge Keith F. Giblin
	§	
QUAN EMERTEQ CORP., d/b/a ENPATH MEDICAL,	§	
	§	
Defendant/Counter-Plaintiff.	§	

QUAN EMERTEQ CORP. d/b/a ENPATH MEDICAL'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW AND MOTION FOR A NEW TRIAL

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Pursuant to Rules 50(a) and 59(a) of the Federal Rules of Civil Procedure, the Defendant and Counter-Plaintiff, Quan Emerteq Corp. d/b/a Enpath Medical ("Enpath") hereby makes this motion for judgment as a matter of law and for a new trial and in support shows the Court as follows:

I. INTRODUCTION AND SUMMARY

The Plaintiff and Counter-Defendant Pressure Products Medical Supplies, Inc. ("Pressure Products") and Enpath have concluded their respective cases, including Pressure Products' case on rebuttal, and all evidence has been presented to the jury. The totality of the evidence submitted to the jury made clear that no legally sufficient evidentiary basis exists for a reasonable jury to find for Pressure Products on any of its claims. Further, the manifest weight of the evidence made clear that no reasonable jury could find that U.S. Patent Number 5,125,904 (the "904 Patent") or U.S. Patent Number 5,312,355 (the "355 Patent") (collectively, the "Patents-in-Suit" or the "Lee Patents") are valid and thereby find against Enpath on its counterclaim for declaratory judgment that the Patents-in-Suit are invalid.

The claims of the Patents-in-Suit at issue at trial were claims 1-11, 13-17 and 20-26 of the '904 Patent and 1, 2, 4, 5, 7, 11, 14-21, 23-25, and 29 of the '355 Patent. At the close of Plaintiff's evidence Enpath filed a Motion for Judgment as a Matter of Law (Docket No. 184) on the following issues: (1) no infringement of claims 13, 14, 15, 16, and 17 of the '904 Patent; (2) no infringement of claims 1, 2, 3, 5, 7, 11, 14-18, and 20 of the '355 Patent; (3) no willful infringement; and (4) invalidity of the '904 and '355 Patents. (Trial Tr. vol. 4, 856:21-858:2, 865:3-866:7, 868:18-869:9, 986:25-987:11, 996:17-20, 998:5-9).

After a hearing, the Court granted Enpath's motions for judgment as a matter of law of no infringement of claims 13, 14, 15, 16, and 17 of the '904 Patent and claims 14, 15, 16, 17, and 18 of the '355 Patent. (Trial Tr. vol. 4, 867:16-20, 991:2-3). Additionally, Plaintiff withdrew

claims 4-8 of the '904 Patent. (Trial Tr. vol. 4, 1005:7-10). Therefore, the remaining claims that went to the jury were claims 1-11 and 20-26 of the '904 Patent and claims 1-2, 11, 19-21, 23-25 and 29 of the '355 Patent.[1] The jury found that Enpath infringed each of these claims and that the Patents-in-Suit are valid. Accordingly, Enpath files this renewed Motion for Judgment as a Matter of Law and respectfully requests that the Court overturn the jury's finding of infringement and validity of the Patents-in-Suit and declare that the Patents-in-Suit are invalid. Alternatively, Enpath requests a new trial. In seeking this relief, Enpath incorporates herein by reference its prior Motion for Judgment as a Matter of Law. (Docket No. 184).

II. STANDARD AND GROUNDS

The Court may render judgment as a matter of law against a party who, after being fully heard, provides no facts constituting a prima facie case and does not meet its burden of production. *See* FED. R. CIV. P. 50(a)(1). Judgment should occur where "there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). A judgment as a matter of law should be granted "not only when the non-movant presents no evidence, but also when there is not a sufficient conflict in substantial evidence to create a jury question." *Travis v. Bd. of Regents of Univ. of Tex. Sys.*, 122 F.3d 259, 263 (5th Cir. 1997), *cert. denied*, 522 U.S. 1148 (1998). "'Substantial evidence is more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1363 (Fed. Cir. 2004) (quoting *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)).

[1] Significantly, none of the remaining claims include or require the use of a side arm for flushing the introducer sheath.

Based upon these legal standards, Enpath moves this Court to enter judgment as a matter of law, or, in the alternative, for a new trial, on the following grounds:

- The erroneous construction of the claims of the Lee Patents resulted in the jury's finding of literal infringement, and no legally sufficient evidentiary basis otherwise existed for a reasonable jury to find literal infringement;

- The Court's reconstruing of the term "score line" during trial and after Enpath's cross examination of Pressure Products' infringement expert, Joe Thomas, severely prejudiced Enpath's defense as a whole;

- The totality of the evidence presented to the jury clearly and conclusively demonstrates that the Lee Patents are invalid as anticipated by the Haindl '600 Patent and obvious in light of the Haindl '915 patent, the Haindl '600 patent and the Stevens '739 patent.

The Court's entering of judgment as a matter of law will dispose of all affirmative claims for relief and relieve the jury of any duty to decide claims in this case.

III. ARGUMENT AND AUTHORITIES

A. Pressure Products Offered No Legally Sufficient Proof of Literal Infringement and All Substantial Evidence Negates Infringement.

1. Enpath is Entitled to a New Trial Because the Manner in Which the Court Revised the Construction of "Score Line" was Highly Prejudicial and Manifestly Unfair to Enpath, Tainting its Entire Defense.

This Court may grant a new trial "for any reason for which a new trial has heretofore been granted in an action at law in federal court." FED. R. CIV. P. 59(a)(1)(A). A motion for new trial "may invoke the discretion of the court in so far as it is bottomed on the claim that the verdict is against the weight of the evidence, that the damages are excessive, or that, for other reasons, the trial was not fair to the party moving; and may raise questions of law arising out of alleged substantial errors in admission or rejection of evidence *or instructions to the jury*." *QPSX Devs. 5 Pty. Ltd. v. Nortel Networks, Inc.*, No. 2:05-CV-268, 2008 WL 728201, at *3

(E.D. Tex. Mar. 18, 2008) (quoting *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 251 (1941)) (emphasis added).

Another ground for a new trial is unfair surprise. *Genmoora Corp. v. Moore Bus. Forms, Inc.*, 939 F.2d 1149, 1156 (5th Cir. 1991). In patent actions, yet another basis for a new trial is the use of an incorrect claim construction at trial. As the Federal Circuit recently recognized, "[w]here an infringement verdict relies on incorrect construction of the disputed claim terms, this court may grant JMOL or order a new trial to correct the error." *Finisar Corp. v. The DirecTV Group, Inc.*, 523 F.3d 1323, 1333 (Fed. Cir. 2008). When surprise or an incorrect construction have prejudiced the moving party, a new trial is warranted. In general, a new trial may be ordered for any reason the trial was not fair to the moving party. *Winger v. Winger*, 82 F.3d 140, 143 (7th Cir. 1996).

A new trial is warranted here for three reasons. First, the Court on its own initiative re-construed the claim term "means for permitting removal"[2] through a new interpretation of "score line". This term had already been construed by the Court, the construction of which was part of its March 19, 2008 Memorandum Opinion and Order Construing Claim Terms of United States Patent Nos. 5,125,904 and 5,312,355 from the *Markman* hearing (the "*Markman* Order"). (Docket No. 89). Moreover, the construction of "score line" adopted by the Court was the construction proposed by Pressure Products during *Markman* briefing and is premised on the same claim interpretation methodologies that the Court previously rejected in its *Markman*

[2] There are three means-plus-function limitations at issue: (1) means for permitting removal of said hemostatic valve and introducer sheath from said lead or catheter disposed therethrough; (2) means for splitting said introducer sheath and hemostatic valve away from said lead or catheter which is disposed therethrough; and (3) means for peeling away said introducer sheath and hemostatic valve from said lead or catheter which is disposed therethrough. In each of these means-plus-function limitations, the corresponding structure is "score lines defined in the hemostatic valve and introducer sheath, and equivalents thereof." The Court's re-construction of "score line" resulted in expanded construction for each of these means-plus-function limitations. For the sake of convenience, Enpath refers to the three means-plus-function limitations at issue as the "means for permitting removal" limitation.

Order. Second, the construction of "score line" entered by the Court usurped the jury function of determining whether the structure in the accused product is the same or the equivalent to the corresponding structure in the patent. The re-construction of the claim term "score line" and importing this definition into the definition of "means for permitting removal," effectively resulted in entry of judgment as a matter of law in favor of Pressure Products on infringement. Third, even if the Court's re-construction of the means-plus-function claim was procedurally proper, the re-construction was substantively erroneous. The construction was based on application of claim differentiation, which in the means-plus-function context is trumped by 35 U.S.C. § 112. Moreover, the scope of the term was expanded through reliance on prior art that was disparaged by the patent applicant as not offering the critical features of the claimed invention, such as hemostasis and easy removability. As such, the jury's finding of infringement rested on an improper construction.

These errors unfairly prejudiced Enpath on multiple fronts. The revised construction negated Enpath's ability to offer expert testimony on non-infringement, both literal and under the doctrine of equivalents. Also, Enpath's entire invalidity defense hinged upon the construction found in the Court's *Markman* Order. Had the Court at that time adopted Pressure Products' proposed construction, Enpath would have based its invalidity defense on a broader range of invalidating prior art. Finally, Enpath's inability to offer evidence of non-infringement had the inescapable effect of tainting the jury. This is precisely the position in which Enpath was placed following the re-construction of the claims. The Court's modified claim construction unfairly prejudiced Enpath, entitling Enpath to a new trial.

2. The Timing of the Court's Re-Construction of the Means-Plus-Function Claims Prejudiced Enpath.

The Court's re-construction of the "means for permitting removal" limitations through its revised construction of the term "score line" following Enpath's cross-examination of Pressure Products' expert Joe Thomas was erroneous and prejudicial to Enpath. Thomas' testimony was clear – cuts, slits, slots, tears, etc., are not "score lines." (Trial Tr. vol. 3, 554:23-555:17). Indeed, Mr. Thomas' working definition of "score lines" was:

> [A] weakening line down the length of the sheath. This weakening could be effected either by a split partway through the wall or could be by way of removal of some material.

(Thomas Dep. 62:3-10, June 25, 2007, read into the record at Trial Tr. vol. 3, 704:9-18; vol. 5, 1016). The merits of the re-construction of the means for removal limitation aside, the manner and timing of the Court's decision to re-construe the claims as proposed by Pressure Products was highly prejudicial to Enpath. At the close of Pressure Products' case-in-chief, Pressure Products had adduced no evidence upon which a jury could find that the accused products literally infringe claims of the patents-in-suit. The Court recognized as much. During the hearing held toward the end of Pressure Products' case-in-chief, the Court indicated that there was no evidence of direct infringement and that the case would come down to the jury deciding infringement under the doctrine of equivalents. (Trial Tr. vol. 3, 712:19-713:3).

Although Enpath would have offered testimony of its own as to why the accused products do not infringe the Patents-in-Suit under the doctrine of equivalents in the context of the "means for permitting removal" limitation, it never got the chance. At that juncture, the Court on its own initiative re-construed the "means for permitting removal" limitation. The Court had previously construed the structural component of the "means for permitting removal" limitation as "score lines defined in the hemostatic valve and introducer sheath, and equivalents thereof." The Court

had also previously interpreted "score line" to mean "one or more line(s) defined in said hemostatic valve and introducer sheath." (Docket No. 89 at 14).

Guided by the Eastern District of Texas case *O2 Micro International Ltd. v. Beyond Innovation Technology Co., Ltd.*, the Court found it necessary to enter a new construction of "means for permitting removal" through a new "score line" limitation. The Court entered new constructions of these terms, which were essentially identical to the constructions urged by Pressure Products during the *Markman* process. In its *Markman* Order, the Court correctly rejected Pressure Products' attempts to rewrite its means-plus-function claims in non-means-plus-function form through reliance on disparaging prior art and claim differentiation. Yet at the close of Pressure Products' case-in-chief, while recognizing that the record was devoid of any evidence that the accused products contain the claimed "means for permitting removal", the Court adopted Pressure Products' construction. Enpath respectfully submits that this was erroneous.

Under the circumstances at trial, the Court was not required under *O2 Micro International* to enter a new construction of the "means for permitting removal" limitation. In that case, the district court declined to construe the claim limitations "only if," the meaning of which the parties disputed. Instead, the district court left for the jury to decide if the accused product infringed the asserted claim based on the jury's interpretation of the phrase "only if." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1357-58 (Fed. Cir. 2008). Following the jury's own interpretation of the phrase "only if," it found that the accused devices literally infringed the patent-in-suit. *Id.* at 1358. On appeal, the defendant argued (and the Federal Circuit agreed) that the district court improperly submitted to the jury the construction of the phrase "only if." *Id*. at 1360-62. The district court, rather than the jury, is in

the best position to determine the scope of a claim term that is in dispute and was not otherwise construed. *Id.* at 1362-63.

Here, the Court was in no way faced with the jury interpreting the "means for permitting removal" or "score line" limitations. The Court had already construed those terms. If properly instructed based on the *Markman* Order construction that "means for permitting removal" is a "score line" and that a "score line" is "one or more lines," which is where the case stood prior to the Court revisiting the issue, then the concerns of *O2 Micro International* would not have been implicated. Once properly instructed in this manner, the jury could have weighed the evidence presented to determine if the structure of the accused devices was the same or the equivalent of a relevant structure.

A claim construction that is not in dispute is to be left undisturbed. *See Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d 136, 842 (Fed. Cir. 1999) (declining to *sua sponte* revise settled construction not challenged by the parties). By reversing course on the previously entered construction, which was not in dispute, numerous prejudicial errors ensued. First, at the critical juncture, Pressure Products had lodged no objection or made no motion for the Court to revisit the construction of the relevant limitations. The parties' *Markman* briefing concluded months before trial, the parties were heard on their respective claim construction positions, and the Magistrate Judge entered a claim construction order. Pressure Products made no objection to the District Judge to this construction, and offered no alternative construction in its summary judgment motion of infringement, in the pre-trial proceedings, or at trial. Nevertheless, the Court, *sua sponte* entered a new meaning of the claim terms.

3. The Court's Revised Construction Negated the Jury's Fact-Finding Function.

The Court's revised construction also usurped the jury's function of determining whether the structure in the accused product is the same or the equivalent to the corresponding structure

in the patent that performs the function. *See Asyst Techs., Inc. v. Empale, Inc.*, 268 F.3d 1364, 1373 (Fed. Cir. 2001) (whether a device infringes a means-plus-function claim is a question of fact).

Next, by entering the construction originally proposed by Pressure Products, the trial swung from one extreme (no evidence of literal infringement) to another by virtually entering a judgment as a matter of law of infringement in favor of Pressure Products. Based on the revised construction of the "means for permitting removal" limitation, which went beyond a "line" as disclosed in the patent specification, but included a "linear perforation; slit; slot; tab; line; severing; weakening; or tear that can be partial or complete," the jury was left with no room to give any real consideration to the question of infringement. The Court's revised construction short-circuited the need for the jury to determine whether the accused products contained a structure that is the same or equivalent of the structure disclosed in the patent specifications. In essence, the revised construction had the added effect of making literal infringement a foregone conclusion. In light of this erroneously entered construction, any attempt by Enpath to offer evidence that the accused devices did not include the claimed "means" was virtually futile. Any attempt to adduce evidence that the products did not infringe under the doctrine of equivalents became pointless.

The Court's revised construction alone broadened the scope of the Patents-in-Suit. A broad construction increases the patent's coverage from an infringement standpoint and at the same time leaves the patent more susceptible to an invalidity challenge. The "double-edged sword" nature of the broad construction, however, was only felt by Enpath. Had the Court adopted Pressure Products' broad proposed construction in its *Markman* Order, Enpath would have been able to mount a corresponding challenge to the patents' invalidity. By revising the

construction on the eve of Enpath's case-in-chief, however, Enpath was forced to proceed with evidence of invalidity that comported with the original narrow construction. Armed with this broad construction ahead of time, Enpath could have invalidated the patents through numerous avenues, especially in view of the *KSR International Co. v. Teleflex, Inc.* standard for obviousness. Instead, Enpath's evidence of invalidity, presented through its expert Dr. Ethan Podet, was premised on the Court's prior construction. As a result of the Court's change in course, Pressure Products was able not only to reap the benefits of the broad construction from an infringement standpoint, but also to avoid leaving the patents equally susceptible to invalidity based on anticipation or obviousness. Enpath respectfully submits that this change of construction resulted in a high degree of prejudice and warrants a new trial.

4. The Court Erred in its Revised Constructions of "Means for Permitting Removal" and "Score Line" Limitations.

Finally, even if the procedural context in which the revised constructions were entered was proper or not prejudicial, the actual revised construction was erroneous. The determination of whether the accused Enpath products infringe the Patents-in-Suit turns, at least in part, on the Court's construction of the limitation "means for permitting removal." This limitation permeates the asserted claims that went to the jury on the issues of infringement and invalidity.[3] Once the Court held that *O2 Micro International* required it to re-construe the "means for permitting removal" and "score line" limitations and those limitations were so construed, the jury was instructed to apply improperly construed claims to the accused products.

The Court's construction of the limitation "means for permitting removal" does not comply with the mandate of 35 U.S.C. § 112, ¶ 6. Patent claims drafted in means-plus-function

[3] The various method claims of the Patents-in-Suit that do not contain the "means for permitting removal" limitation were otherwise dismissed pursuant to Enpath's motion for JMOL of non-infringement made during trial.

format under § 112, ¶ 6 are construed in light of the structures disclosed in the patent's specification for performing the recited function. *Chiuminatta v. Concrete Concepts, Inc.*, 145 F.3d 1303, 1308 (Fed. Cir.1998). The patent applicant's use of the convenience of drafting patent claims in means-plus-function format comes at a price. While "ordinary" claim terms must not be construed narrowly by importing embodiments from the specification into the claims, this is precisely what a means-plus-function claim requires. *B. Braun Med., Inc. v. Abbott Labs*., 124 F.3d 1419, 1424 (Fed. Cir.1997). This requirement comes with very strict prohibitions against construing a means-plus-function claim too broadly. A means-plus-function claim covers structures expressly cited in the patent specification that perform the recited function, and nothing more. *Id*. An accused device literally infringes a means-plus-function claim if the structure in the accused product for carrying out the function is the same or equivalent to the corresponding structure in the patent. *Chiuminatta*, 145 F.3d at 1309. A clear link between the structure disclosed in the specification for carrying out the recited function is the *quid pro quo* for the convenience of employing means-plus-function claim language. *B. Braun Med.*, 124 F.3d at 1424.

The Court construed the structural component of the "means for permitting removal" limitation as covering "score lines defined in the hemostatic valve and introducer sheath, and equivalents thereof." Originally, the Court also construed "score line" as "one or more line(s) defined in the hemostatic valve and introducer sheath." The Court, after the close of Pressure Products' case-in-chief, re-construed "score line" to mean "linear perforation; slit; slot; tab; line; severing; weakening; or tear that can be partial or complete." Construing "score line" in this manner yielded a construction of the various means claims to mean " a linear perforation; slit; slot; tab; line; severing; weakening; or tear that can be partial or complete for permitting

removal of the hemostatic valve and introducer sheath from the lead or catheter." This construction violates the mandate of 35 U.S.C. § 112, ¶ 6 because there is no disclosure in the specifications of the patents-in-suit of a "linear perforation; slit; slot; tab; line; severing; weakening; or tear that can be partial or complete" that is linked to the recited function of "permitting removal of the hemostatic valve and introducer sheath from said lead or catheter disposed therethrough." The Court agreed with this conclusion in the original *Markman* Order

In support of this construction, the Court pointed to various prior art references discussed in the background sections of the '904 and '355 Patents. This discussion in each patent, however, disparages prior art sheath assemblies and hemostatic valve units by failing to be removable without sliding over the end of the catheter and by failing to be leak-free. These are the functions that the means-plus-function claims at issue are directed to perform. When a patent specification disparages the prior art because it fails to perform the functions recited in the means-plus-function claim, an interpretation of the claim to encompass the prior art is erroneous. *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1220 (Fed. Cir.1996). The Court's re-construction of the "means for permitting removal" limitations was based on this reliance on the discussed prior art rather than the structure disclosed in the specification that is clearly linked to the recited function. As such, the Court improperly instructed the jury on the meaning of these means-plus-function claims.

Moreover, the Court applied the doctrine of claim differentiation to arrive at a exceedingly broad construction of the "means for permitting removal" limitation. The Court pointed to claim 4 of the '904 patent that recites "whereby the means for permitting removal …is a score line" and concluded that since claim differentiation requires that different claims are presumptively of different scope, the structural component of the claimed "means for permitting

removal" limitations must be construed in a way that encompasses more than the only structure disclosed in the specification – a score line. The Court's application of claim differentiation in this context was incorrect. The judicially created doctrine of claim differentiation is trumped by the statutory requirements of 35 U.S.C. § 112, ¶ 6. *See Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991) (rejected broadening of means-plus-function claim through claim differentiation). The '904 patent's disclosure of only a single structure for permitting removal is not expanded to encompass more than the patent specification discloses simply because a dependent claim recites that single structure. Indeed, the Federal Circuit recognizes this as a convenient trick for claim drafters (and future litigators) to avoid the strictures of 35 U.S.C. §112, ¶ 6. *Id.* Accordingly, the Court's construction of the "means for permitting removal" limitation was driven by claim differentiation and is therefore erroneous.

5. The Uncontroverted Evidence was Contrary to the Court's Revised Construction.

The uncontroverted evidence offered at trial runs contrary to the Court's revised construction. Pressure Products' own witness, Dr. Goldreyer, testified that a "score" and a "cut" through the PTFE sheath are not structural equivalents—they are two different things. In the words of Dr. Goldreyer,

> [B]ack at that time there were basically only two ways, your Honor. That was a surface score or a cut through the top of a PTFE sheath, at least in clinical practice.

(Trial Tr. vol. 3, 691:21-24).

The Court recognized that the only structure disclosed in the Patents-in-Suit for "removing," "peeling" or "splitting" the introducer sheath is a "score line:"

> I think this is, in fact, a correct statement of the structure that is disclosed in the '904 patent, "score lines defined in the hemostatic valve."

> And then in the '355 patent, when that same phrase or term is used, it starts off with "one or more score lines." So, that is the structure.

(Trial Tr. vol. 3, 682:22-683:3). Despite the fact that PTFE sheaths were known in the art at the time, the use of a PTFE sheath for "removing," "peeling" or "splitting" the introducer sheath of the Patents-in-Suit was not a disclosed structure within the meaning of 35 U.S.C. § 112, ¶ 6. (Docket No. 89 at 23).[4]

Further, the Court's new definition, did not take into consideration the only evidence before the Court concerning what one of ordinary skill would understand "score line" and "scoring" to be. Specifically, the Court did not fully consider the following:

- The definition of "score" provided during the *Markman* hearing from the *Academic Press: Dictionary of Science and Technology (1992)* which provides as follows: "any scratch, line or groove that is formed by the scoring process" (Docket No. 89 at 14);

- The working definition of "score line" provided by Joseph Thomas – "a weakening line down the length of the sheath. This weakening could be effected either by a split partway through the wall or could be by way of removal of some material." (Trial Tr. vol. 5, 1016:1-8);

- The testimony of Joseph Thomas that a "score" is a "scribe" that does not go all the way through a material and is different than a "cut," which does go all the way through (Trial Tr. vol. 3, 554:23 – 555:17);

- The statement of John Zawacki, Enpath's expert witness on issues of infringement, stating that at the time of the patents-in-suit there were only two ways to split a sheath – PTFE or scoring (Trial Tr. vol. 4, 688:2-20); and

- The statement of Dr. Goldreyer, that "back at that time there were basically only two ways, your honor. That was a surface score or a cut through the top of a PTFE sheath, at least in clinical practice. The drawings might have shown dotted lines or whatever; but, in fact, that was not the case." (Trial Tr. vol. 3, 691:21-692:1).

Significantly, there was no testimony or evidence of any kind to suggest that one of ordinary skill in the art at the time of the Patents-in-Suit would understand a "score line" to include a

[4] Notably, Pressure Products did not move for reconsideration of this Order.

perforation, slit, slot, tab, severing, weakening or tear. Instead, all of the evidence was that these are not "score lines."

6. The Court's Revised Definition of "Score Line" is Contradicted By the Plain Language of the Claims and the Specification of the Patents-in-Suit.

Although claim differentiation may not be involved to rewrite a means-plus-function claim in non-means-plus-function form, it certainly applies when reconciling the construction of different non-means-plus-function limitations. It is axiomatic that when different terms are used in patent claims, may mean different things. As stated by the Federal Circuit in *Helmsderfer v. Bobrick Washroom Equipment, Inc.*:

> Our precedent instructs that different claims terms are presumed to have different meanings. *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 n. 3 (Fed. Cir. 2006) ("[T]he use of two terms in a claim requires that they connote different meanings…."); *CAE Screenplates Inc. v. Heinrich Fiedler GmbH*, 224 F.3d 1308, 1317 (Fed. Cir. 2000) ("In the absence of evidence to the contrary, we must presume that the use of these different terms in the claims connotes different meanings.").

Helmsderfer v. Bobrick Washroom Equipment, Inc., 527 F.3d 1379, 1382 (Fed. Cir. 2008).

For example, in claim 2 of the '355 Patent, the word "cut" is used to define the "means for permitting removal of said hemostatic valve . . . to facilitate parting of said membrane wherein said body portions are pulled apart." (Pl.'s Ex. 2, 10:29-34). In this same claim, the term "score line" is also used to describe the "means for permitting removal." (Pl.'s Ex. 2, 10:11-15). Elsewhere in the '355 Patent, the term "score line" is expressly used. (*See, e.g.*, Pl.'s Ex. 2, 11:68). Under Federal Circuit precedent, the terms "cut" and "score line" presumptively mean two different things. This presumption was confirmed by Thomas, who admitted that a "cut" or "slit" is something that penetrates all the way through a material, (Trial Tr. vol. 3, 556:1-559:23; Pl.'s Ex. 443; Def.'s Ex. 41 at Ex. C, 6) whereas his understanding of "score," is a scribe that does not go all the way through the material. (Trial Tr. vol. 3, 554:23 – 555:17); s*ee*

also Helmsderfer, 527 F.3d at 1382. The foregoing uncontradicted evidence conflicts with the Court's new definition of "score line," which equates score line to:

> [L]inear perforation; slit; slot; tab; line; severing; weakening or tear that can be partial or complete.

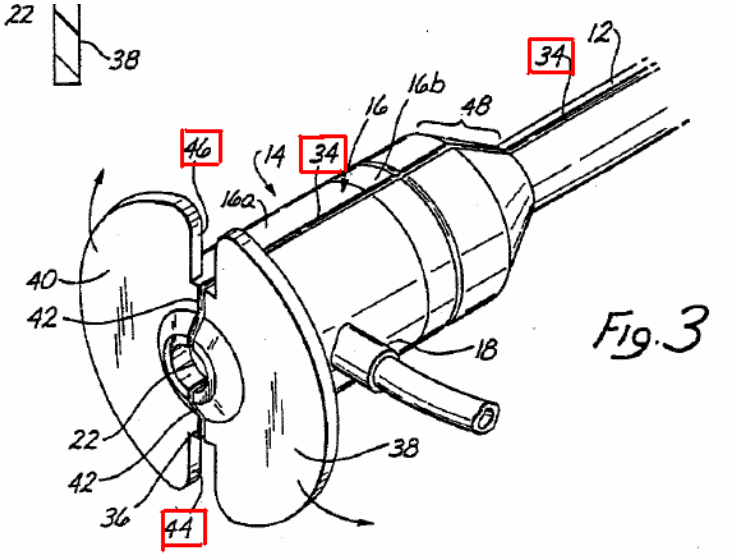
(Trial Tr. vol. 3, 706:19-21). Included in the Court's revised definition are several synonyms for "cut." Specifically, "perforation," "slit," "slot", "severing" and "tear" are all synonymous with a "cut" and in conjunction with the fact that such "slits" and "slots" can be "complete" means that an alteration of the sheath that penetrates all the way through the material can be deemed a "score line." No one in the case, however, offered such testimony.

7. The Error in the Court's Definitions is Reinforced by a Plain Reading of the Specification.

In the '355 Patent, the inventor expressly distinguished between "scores" on the one hand and "slots" on the other hand -- the latter term being expressly included in the Court's revised definition of a "score line":

> In the illustrated embodiment flanges 38 and 40 are formed in two halves having diametrically opposing ***slots*** 44 and 46 aligned with ***score lines*** 34 and 36 defined into valve body 16. *However, it is entirely possible that score lines 34 and 36 will be continued through flanges 38 and 40 to provide* ***deep scores instead of open slots*** *44 and 46.*

(Pl.'s Ex. 2, 8:3-9) (emphasis added).



(Pl.'s Ex. 2, Fig. 3).

Thus, the Court has defined the word "score line" to include a "slot" at the same time that the patentee has explicitly distinguished between these to same concepts. The specification and the claims (which use the terms "cut" and "score" to mean separate things), should control. *B. Braun Med.*, 124 F.3d at 1424.

Further, the Court's revised definition of "score line" leaves the Lee invention largely unenabled. Since the "slits" "slots" "severings" "perforations" and "tears" can, by the Court's definition, go all the way through the width of the material **and** all the way down the side of the sheath the hemostatic valve, such a device will NOT meet the intended purposes of the "whereby" clauses of the patent claims – i.e. keeping blood in and air out. (Pl.'s Ex. 1, 2; *see also* Trial Tr. vol. 3, 587:20-21). Clearly, a construction that defeats the intended purpose of the patent claims is, by definition, not proper.

8. The Evidence Establishes that the Accused Enpath Products do not Include a Hemostatic Valve Comprised of a Two Part Body.

Enpath's motion for judgment as a matter of law that Enpath does not infringe claims 1, 2, 11 and 20 of the '355 Patent should be granted because the indisputable evidence establishes

that the hemostatic valves of the accused Enpath devices include three, not two, parts. Claims 1, 2, 11[5] of the '355 Patent require that

> said means for permitting removal of said hemostatic valve comprises a two-part body, … said body portions defining means for sealing said body portions together *when said two body parts are joined with each other to form said hemostatic valve*.

(Pl.'s Ex. 2, '355 Patent claim1) (emphasis added). Similarly, claim 20, which depends from claim 19 requires that

> 19. . . . said means for permitting removal of said hemostatic valve comprises a multiple-part body . . . said body portions defining means for sealing said body portions together *when said body parts are joined with each other to form said hemostatic valve*.
>
> 20. The sheath assembly of claim 19 wherein said multiple-part body is a two-part body.

(Pl.'s Ex. 2, '355 Patent claims 19-20) (emphasis added). By their very language, claims 1, 2, 11 and 20 of the '355 Patent require a "hemostatic valve" that is comprised of "two body parts" whereby the "two body parts are joined with each other to form said hemostatic valve." (Pl.'s Ex. 2, '355 Patent claims 19-20).

The uncontroverted evidence provided by Pressure Products' own witnesses, however, establishes that the hemostatic valves of the accused Enpath devices have three, not two, body parts – a top portion, a bottom portion, and a membrane. (Trial Tr. vol. 2, 294:17-301:21; vol. 3, 611:25-616:9). Pressure Products' own witnesses admitted that without all three parts – the top portion, the bottom portion and the membrane – of the accused devices, there was **no** hemostatic valve. (Trial Tr. vol. 2, 294:17-301:21; vol. 3, 611:25-616:9). Consequently, because the uncontroverted evidence establishes that the hemostatic valves of the accused products contain

[5] Claims 2 and 11 of the '355 Patent depend from claim 1 of the '355 Patent.

three, not two, body parts, Enpath's motion for judgment as a matter of law of no infringement of claims 1, 2, 11 and 20 of the '355 Patent should be granted.

B. All Substantial Evidence Conclusively and Clearly Demonstrates the Invalidity of the Lee Patents As a Matter of Law.

A finding of patent validity by a jury in a federal district court in Texas is reviewed under the "substantial evidence" rule. *See ACCO Brands, Inc. v. ABA Locks Mfr. Co. Ltd*, 501 F.3d 1307, 1311 (Fed. Cir. 2007). Once evidence is presented at trial that establishes a prima facie case of invalidity, the patentee must come forward with evidence to counter the prima facie challenge. *Scanner Techs. Corp. v. Icos Vision Sys. Corp. N.V.*, Nos. 2007-1399, 2008-1081, 2008 WL 2468487, at *11 (Fed. Cir. June 19, 2008). The finder of fact then determines whether the challenger has met its burden by clear and convincing evidence by considering the totality of the evidence, which includes all rebuttal evidence. *Scanner Techs.*, 2008 WL 2468487 at *11. The totality of the evidence offered at trial makes clear that that the Lee Patents are anticipated and rendered obvious by the prior art, and no reasonable jury could find otherwise.

1. The Lee Patents Are Invalid Because All Claims are Anticipated by Prior Art.

The patent claims asserted by Pressure Products against Enpath are invalid because they are anticipated by a source of prior art. A patent is anticipated if "the invention was patented or described in a printed publication in this or a foreign county or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. § 102(b). Anticipation invalidates a patent "if a single prior art reference discloses each and every limitation of the claimed invention" and describes the invention adequately enough to place it in the possession of a person skilled in the art. *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003); *Helfix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed Cir. 2000). Additional references may be used to prove the contents of the anticipating prior art but

may not be used to supply missing claim limitations. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1335 (Fed. Cir. 2002). Even if a prior art reference does not directly disclose a feature of the claimed invention, a reference can anticipate a patent "if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering*, 339 F.3d at 1377. Proving inherent anticipation "does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure." *Id*.

All substantial evidence is consistent and clear and convincing that each of the asserted claims in the Lee Patents are anticipated by German Patent Number 3834600 (the "Haindl '600 Patent"). Enpath's testifying expert on invalidity, Dr. Ethan Podet, demonstrated that the Haindl '600 Patent includes every element of every claim of the patents-in-suit.[6] (Trial Tr. vol. 4, 840:11-15). To aid the jury, Dr. Podet prepared claim charts comparing every element of every claim that is at issue in this case to the Haindl '600 Patent. (Def.'s Exs. 120-122). In these charts, Dr. Podet quotes the language from the Haindl '600 Patent that corresponds to each element of each asserted claim of the patents-in-suit. (Def.'s Exs. 120-122). Dr. Podet also provided a copy of the English translation of the Haindl '600 Patent on which he highlighted all of the language that he quoted in his claim charts. (Def.'s Ex. 252). Dr. Podet walked the jury through his charts by comparing each element of claim 1 of the '904 Patent with the language of the Haindl '600 Patent. (Trial Tr. vol. 4, 902:20-920:25). In rebuttal, Pressure Products produced no competent or substantial evidence to counter Dr. Podet's testimony; indeed, Pressure Products did not challenge the accuracy or completeness of Dr. Podet's claim charts, his testimony regarding how to read them or their import – either before the trial by a *Daubert* motion or during trial on cross. This entitles Enpath to judgment as a matter of law on invalidity.

[6] Dr. Podet testified that those claims of the '904 Patent that require a sidearm, claims 13-17, were not anticipated by Haindl. (Trial Tr. vol. 4, 922:4-16). Claims 13-17 of the '904 Patent are not, however, at issue because the court granted Enpath's motion for JMOL as to its noninfringement of those claims. (Trial Tr. vol. 4, 867:16-20).

Scanner Techs., 2008 WL 2468487 at *11; *Pfizer Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1360 (Fed. Cir. 2007).[7]

2. The Lee Patents are Invalid Because All Claims Are Obvious.

The weight of the evidence at trial established that the Lee Patents are invalid because they are also obvious. A patent claim is invalid if the subject matter would have been obvious in view of prior art at the time the invention was made to one of ordinary skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has made clear that "granting patent monopoly to technological advances that would occur in the ordinary course without real innovation retards progress and deprives prior inventions of their value." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-1741 (2007). Where a patent combines old elements, the question becomes whether one skilled in the art would have combined the exact elements in the same way as the inventor. *Id.* at 1744. Combining familiar elements with known methods is obvious when it yields predictable results. *See Advanceme Inc. v. RapidPay, LLC*, 509 F. Supp. 2d 593, 610 (E.D. Tex. 2007) (citing *KSR*, 127 S. Ct. at 1740-1741). Notably, commercial success cannot overcome strong evidence of obviousness. *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991).

[7] Faced with substantial evidence that the Haindl '600 Patent anticipated the patents-in-suit, Pressure Products argued that the Haindl '600 Patent is not enabled, and, therefore, cannot be anticipating prior art. Pressure Products' argument to this effect is nothing more than a red herring. The test for whether a piece of anticipating prior art is enabled is *de minimis*. When a prior art reference anticipates (or makes obvious), the elements of the claimed invention, the reference is presumed to be operable, and once such a reference is found, a burden arises to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675 (C.C.P.A. 1980). Simply put, a prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; "proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation." *Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1383 (Fed. Cir. 2006). Further, even if this were not the case, Enpath demonstrated through the testimony of both Grant Mauch, an Enpath engineer, and Joe Thomas, Pressure Products expert on infringement, that the Haindl '600 Patent was, in fact, enabled.

All substantial evidence at trial was consistent, clear and convincing that adding a splittable hemostatic valve to a splittable sheath was an ordinary advance in the evolution of introducers. Splitting sheaths and hard plastic handles was well known in the art. (*See, e.g.*, Def.'s Ex. 10, United States Patent No. 4,596,599). Also well known were hemostatic valves made of pliable and relatively flimsy material that were easily split. (Def.'s Ex. 1, United States Patent No. 4,000,739). It is undisputed that the only point of alleged novelty of the Lee Patents was the combining of already known splittable introducer sheaths with the already known pliable (and thus splittable) hemostatic valves. (Def.'s Ex. 19 at 77; Trial Tr. vol. 4, 850:20-851:6, 842:7-9). Clear and convincing evidence established that this combination was at most nothing more than a claimed advance that occurred in the ordinary course of the development of these devices.

Dr. Goldreyer, Pressure Products' expert, testified that at the time of the '904 patent, there was already a technique for controlling blood flow out of an unvalved introducer sheath, i.e. pinching off the end of the tube. (Trial Tr. vol. 2, 163:15-20). He also testified that there were already splittable, unvalved introducer sheaths and valved introducer sheaths on the market. (Trial Tr. vol. 2, 197:8-198:21). Adding the known, pliable valve into a known splittable sheath and handle combination was, therefore, an obvious solution. Indeed, as acknowledged in the '904 Patent itself, "[a] hemostatic valve combined with a splittable sheath" was already known in the art. (Def.'s Ex. 20, the '904 Patent, 2:28-32). Thus, Lee admits that he is allegedly "inventing" the next step in the ordinary evolution of these devices: making the *valve* splittable by building it into the handles of an otherwise splittable sheath.

Furthermore, the Haindl '600 Patent provides three different examples of a splittable hemostatic valve. (*See* Def.'s Ex. 4, Figs. 1-4 (30), Fig. 6 (130), Fig 8 (230)). Indeed, the Haindl '600 patent describes the splittable valve repeatedly throughout the text of the patent:

- A valve means comprised of an elastic rubber (or rubber like) cup body (30) which is open at its rear end (Def.'s Ex. 4 at 1);
- Preferably, the cup body is comprised of silicone rubber material or an elastomer which has a low notch strength (in the notch test), e.g., Kraton®, so that it is easy to tear the cup body into two pieces (Def.'s Ex. 4 at 4);
- Means may be provided to facilitate ripping open the cup body 230 as well, e.g. at a weakened locus or by the choice of a suitable material (Def.'s Ex. 4 at 12).

Substantial and competent evidence established that adding a splittable valve to an otherwise splittable introducer sheath was obvious. The Haindl '600 alone, or in combination with the Haindl '915 and the Stevens '739 patents, teach every element of every asserted claim. (Def.'s Exs. 1, 4 and 6). No reasonable jury could find otherwise.

3. Pressure Products Offered No Rebuttal Evidence of Validity Sufficient to Overcome the Substantial Evidence of Invalidity Enpath Offered.

Pressure Products' entire validity case at trial rested on the ambiguous statement in the declaration of Dr. Hans Haindl submitted:

> There is no tear-away or controllably splittable hard plastic valve body 12, 212, <u>*shown*</u> in my patent, Haindl '600.

(Def.'s Ex. 11, ¶ 5) (emphasis added). This mere statement is not legally sufficient to rebut Enpath's prima facie case of invalidity offered through the testimony of Dr. Podet.

Dr. Podet presented to the jury three claim charts and a highlighted version of the Haindl '600 patent. (Def.'s Ex. 120-122, 252). In these four exhibits, Dr. Podet conclusively demonstrated that the Haindl '600 patent anticipated every element of every claim that was

submitted to the jury. Dr. Podet showed that the Haindl '600 patent does disclose a splittable valve body:

> After placement of the catheter 10, the plastic capillary 211 is removed from the blood vessel and is broken off [(to ensure that it is not re-used)]. To facilitate this, the plastic capillary 211 and [sic] the capillary holding piece 212 are provided with a ***breaking arrangement ("separating line")*** formed in them. Means may be provided to facilitate ripping open the cup body 230 as well, e.g. at a weakened locus or by the choice of a suitable material.

(Def.'s Ex. 4 at 12).

On the critical issue of whether the prior art showed a "score line," such a score line was plainly shown—in addition to being disclosed in the text—in the drawings of the Haindl '915 patent. (Def.'s Ex. 8). The score line of the Haindl '915 patent provides precisely the "means of removing" that Pressure Products attempted to argue was missing from the Haindl '600 patent.

Pressure Products' expert on invalidity, Dr. Eli Gang, admitted that the Haindl '600 patent showed a valve. (Trial Tr. vol. 3, 672:3-6). However, he "opined" that the Haindl valve was not hemostatic and not splittable. (Trial Tr. vol. 3, 672:6-8). But Dr. Gang's testimony is flatly contradicted by the plain language of the Haindl '600 patent itself. As for whether the Haindl '600 patent's valve was hemostatic, the Haindl '600 specification could not have been clearer:

> Following a successful puncturing, the steel canula is withdrawn, and the pre-stressed bottom region [of ***the cup body] closes off spontaneously, so that no blood flows rearward.***

(Def.'s Ex. 4 at 3) (emphasis added). As for whether the Haindl '600 patent's valve (or cup) was splittable, the uncontradicted statements from the Haindl '600 patent specification demonstrates that it was. (Def.'s Ex. 4 at 12). Dr. Gang's testimony failed to defeat Enpath's prima facie case of invalidity.

Based on the totality of the evidence offered at trial on invalidity, no reasonable jury could find that the Lee Patents were valid because all elements were shown in the prior art, or the combination of sources of prior art, rendering the claimed invention obvious and thereby necessitating judgment as a matter of law. *See Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1338 (Fed. Cir. 2005).

IV. Conclusion and Prayer

WHEREFORE, PREMISES CONSIDERED, the Defendant and Counter-Plaintiff Quan Emerteq Corp. d/b/a Enpath Medical respectfully prays that the Court grant its Motion for Judgment as a Matter of Law, or for a new trial, direct a verdict in its favor, render judgment that the Plaintiff take nothing, declare the Lee Patents to be invalid, and grant Enpath such other and further relief to which it shows itself entitled.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was served on all counsel of record in accordance with the Federal Rules of Civil Procedure and the Local Court Rules of the United States District Court for the Eastern District of Texas, on this 3rd day of July, 2008.

/s/ Chris L. Gilbert